IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ESTELLE GELLER, on behalf of herself

and all others similarly situated,

Plaintiff, : NO.

v. : CLASS ACTION COMPLAINT

FOR INJUNCTIVE RELIEF AND

WYETH, Individually, and D/B/A : DAMAGES

WYETH-AYERST RESEARCH,

Defendant. : <u>JURY TRIAL DEMANDED</u>

Plaintiff, by and through her attorneys, alleges as follows:

SUMMARY OF CLAIMS

- 1. Plaintiff brings this national class action, on her own behalf and as representative of a class of persons and consisting of all persons in the United States who are/were prescribed the drug Prempro (chemically known as conjugated estrogens/medroxyprogesterone acetate), or their estates, administrators, or other legal representatives, heirs, or beneficiaries.
- 2. Plaintiff brings this action individually and as class representative to recover damages for deaths and personal injuries, restitution, refunds, and/or for equitable, injunctive, and declaratory relief against defendant, Wyeth and Wyeth d/b/a Wyeth-Ayerst Research (collectively "defendants" or "Wyeth"), which tested, marketed, distributed, promoted, and sold Prempro. On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLBI"), an agency with the federal government and part of the National Institutes of Health ("NIH"), halted a major clinical trial of the risks and benefits of hormone replacement therapy involving estrogen and progestin in healthy postmenopausal women. The drug used during the trial was Prempro, supplied by Wyeth. The

16,600-patient study was abruptly halted after researchers said the risks of taking Prempro outweighed its benefits.

3. The primary goals of this class action are to (1) inform the public that users and consumers of Prempro are at an increased risk of harm, (2) establish a medical monitoring fund so that every consumer may be tested and treated for the adverse effects of Prempro, (3) reimburse monies paid for the product, and (4) provide compensation to all victims for personal injuries and/or death.

PARTIES

- 4. Plaintiff, Estelle Geller, is a resident of the state of Florida, residing in Boca Raton in Palm Beach County. Plaintiff was prescribed, purchased, and used Prempro. Plaintiff has ingested Prempro for over ten (10) years. To date Plaintiff has not been diagnosed, and is unaware of having an injury at this time, but may be at an increased risk of injury as a result of her ingestion of Prempro.
- 5. Defendant, Wyeth, is a Pennsylvania corporation with its principal place of business at 555 East Lancaster Avenue, Wayne, PA, 19087. Wyeth manufactures, markets, and distributes Prempro throughout the United States, including throughout the Eastern District of Pennsylvania.

JURISDICTION AND VENUE

- 6. Plaintiff alleges an amount in controversy in excess of \$75,000 exclusive of interest and costs, as to herself and each member of the class.
- 7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000 as to plaintiff and each member of the class and there is complete diversity of citizenship between the named plaintiff and defendant Wyeth.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a)(1) because Wyeth is headquartered and conducts business in this District and the contacts of Wyeth with this district are sufficient to subject Wyeth to personal jurisdiction herein.

FACTUAL BACKGROUND

- 9. Prempro is a brand name prescription drug used in hormone replacement therapy (HRT). The drug, which falls within a category of drugs known as progestins, contains conjugated estrogens and medroxyprogesterone acetate.
- 10. Prempro is the leading estrogen-progestin combination drug. Millions of women take Prempro to replace hormones lost at menopause, thereby reducing the incidence of post-menopausal symptoms such as hot flashes, night sweats and vaginal dryness.
- 11. Today, Prempro comes in two tablet offerings: 0.625 mg/2.5 mg and 0.625mg/5.0 mg.
 - 12. In the United States alone, three million women take Prempro each day.
- 13. Prempro was first approved for HRT by the FDA on November 17, 1995 at the 0.625mg/2.5mg dosage. On January 9, 1998 the FDA approved the 0.625mg/5.0 mg dosage.
- 14. The Women's Health Initiative (WHI) is a group focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in postmenopausal women.
- 15. Between 1993 and 1998, the WHI enrolled 161,809 postmenopausal women in the age range of 50 to 79 years into a set of clinical trials and an observational study at 40 clinical centers in the United States.

- 16. Included within the clinical trials was a study by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).
- 17. Participants in the NHLBI component of WHI, like most women with a uterus who take hormone therapy, were given progestin in combination with estrogen. The estrogen plus progestin trial of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer. The study did not address the short-term risks and benefits of hormones for the treatment of menopausal symptoms.
- 18. Women enrolled in the estrogen plus progestin study were randomly assigned to a daily dose of estrogen plus progestin (0.625 mg of conjugated equine estrogens plus 2.5 mg of medroxyprogesterone acetate) or to a placebo. The participants receiving the drug (not placebo) received Prempro. Participants were enrolled in the study between 1993 and 1998 at over 40 clinical sites across the country.
- 19. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.

- 20. Then, at the DSMB's meeting on May 31, 2002, the data review revealed for the first time that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk.
- 21. The DSMB's May 31, 2002 recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. Following the NHLBI's decision to stop the study, the NIH and the investigators worked intensively to develop information materials for participants. On July 8, 2002 participants started receiving letters informing them about the results and telling them that they should stop study medications. Participants needed to be contacted by their clinical centers for further counseling and will continue to have clinic visits so that their health outcomes can be followed. All WHI participants, including those in the other study components, are also receiving a newsletter with a summary of the findings and an explanation of risks and benefits.
- 22. Jacques Rossouw, M.D., acting director of the WHI stressed the importance of understanding how the risk to an individual woman can be low, but the risk to the population at large can be great:

The WHI results tell us that during 1 year, among 10,000 postmenopausal women with a uterus who are taking estrogen plus progestin, 8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clots, including 8 with blood clots in the lungs, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to tens of thousands of these serious adverse health events.

- 23. Furthermore, Leslie Ford, M.D., associate director for clinical research at the National Cancer Institute (NCI) Division of Cancer Prevention re-emphasized the risk of Prempro to patients:
 - "The reduction in colorectal cancer risk in the WHI is intriguing, but the balance of harm versus benefit does not justify any woman beginning or continuing to take estrogen plus progestin for this purpose."
- 24. Altogether, the specific study findings for the estrogen plus progestin group compared to placebo included:
 - A 41 percent increase in strokes
 - A 29 percent increase in heart attacks
 - A doubling of rates of venous thromboembolism (blood clots)
 - A 22 percent increase in total cardiovascular disease
 - A 26 percent increase in breast cancer
 - A 37 percent reduction in cases of colorectal cancer
 - A one-third reduction in hip fracture rates
 - A 24 percent reduction in total fractures
 - No difference in total mortality (of all causes)
- 25. On July 9, 2002, the Journal of the American Medical Association (JAMA) released an expedited publication of the July 17, 2002 article entitled, *Risks and Benefits of Estrogen Plus Progesting in Healthy Postmenopausal Women: Principal Results From the Women's Health Initiative Randomized Controlled Trial*, Vol. 288, No. 3, July 17, 2002.
 - 26. The JAMA article summarized the wide-ranging harm caused by Prempro:
 The WHI provides evidence from a large randomized trial that addresses the important issue of whether most women with an intact uterus in the decades

of life following menopause should consider hormone therapy to prevent chronic disease. The WHI enrolled a cohort of mostly healthy, ethnically diverse women, spanning a large age range (50-79 years at baseline). It is noteworthy that the increased risks for cardiovascular disease and invasive breast cancer were present across racial/ethnic and age strata and were not influenced by the antecedent risk status or prior disease. Hence, the results are likely to be generally applicable to healthy women in this age range. At the time the trial was stopped, the increases in numbers of invasive breast cancers, CHD, stroke, and PE made approximately equal contributions to harm in the estrogen plus progestin group compared with placebo, which were not counterbalanced by the smaller reductions in numbers of hip fractures and colorectal cancers.

27. In discussing the overall risks and benefits of the Prempro therapy, the JAMA authors concluded:

At the end of the trial, the global index indicated that there were more harmful than beneficial outcomes in the estrogen plus progestin group vs the placebo group... Over 1 year, 10,000 women taking estrogen plus progestin compared with placebo might experience 7 more CHD events, 8 more strokes, 8 more PEs, 8 more invasive breast cancers, 6 fewer colorectal cancers, and 5 fewer hip fractures. Combining all the monitored outcomes, women taking estrogen plus progestin might expect 19 more events per year per 10,000 women than women taking placebo. Over a longer period, more typical of the duration of treatment that would be needed to prevent chronic disease, the absolute numbers of excess outcomes would increase proportionately. During the 5.2 years of this trial, the number of women experiencing a global index event was about 100 more per 10,000 women taking estrogen plus progestin than taking placebo. If the current findings can be extrapolated to an even longer treatment duration, the absolute risks and benefits associated with estrogen plus progestin for each of these conditions could be substantial and on a population basis could account for tens of thousands of conditions caused, or prevented, by hormone use.

CLASS ACTION ALLEGATIONS

28. Plaintiff brings this action on her own behalf and on behalf of all other persons in the following class (the "Class"):

All persons, their estates, administrators or other legal representatives, throughout the United States who were prescribed, purchased or were otherwise provided, used and/or ingested the drug Prempro, manufactured,

distributed, and/or sold by Defendants from November 17, 1995 to the present ("Class Period").

- 29. Plaintiff seeks certification of the following Subclasses (the "Subclasses"):
- All persons, their estates, administrators or other legal representatives, a. throughout the United States who suffered personal injuries ("Personal injury subclass"):
- All persons, their estates, administrators or other legal representatives, who b. bring this action on behalf of the estate of an individual citizen or resident of the United States who died as a result of ingestion of Prempro during the relevant time period (the "Wrongful Death Subclass");
- All persons, or other legal representatives, throughout the United States who c. seek treatment and reimbursement under a medical monitoring program ("Medical monitoring subclass");
- All persons, their estates, administrators or other legal representatives, heirs d. or beneficiaries, throughout the United States who seek reimbursement for the purchase price of Prempro ("Reimbursement subclass"); and
- All persons, their estates, administrators or other legal representatives, who e. claim relief pursuant to the Consumer Protection Statutes of Pennsylvania and other states with similar laws or such statute(s) as the Court may determine, pursuant to its choice of law analysis, apply to all consumer claims against a specific defendant (the "Consumer Protection Subclass").
- f. Excluded from the Class and Subclasses are defendants, and any parent, subsidiary, or affiliate of the defendants, and their officers, directors, or employees and members of their immediate families.
 - 30. The representative plaintiff is a member of the Class she seeks to represent.

- 31. The Class is so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of members in the above-described class; their exact number and identities being currently unknown to plaintiff, but known to defendants and/or ascertainable from appropriate discovery.
- 32. There are questions of law and fact common to the Class. These common questions include, but are not limited to, the following:
 - a. Whether the risks of taking Prempro outweigh the benefits;
 - b. Whether Prempro was and is toxic and unsafe;
- c. Whether persons who took Prempro are at increased risk of developing serious injuries, including, but not limited to strokes, heart attacks, venous thromboembolism, cardiovascular disease and breast cancer;
- d. Whether there exists monitoring and testing procedures which make early detection and treatment of, *inter alia*, strokes, heart attacks, venous thromboembolism, cardiovascular disease and breast cancer caused by exposure to Prempro possible and beneficial;
 - e. Whether medical monitoring is appropriate;
- f. Whether, in marketing and selling Prempro, Defendants failed to disclose the dangers and risks to the health of persons ingesting the drug;
- g. Whether defendants failed to warn adequately of the adverse effects of Prempro;
- h. Whether defendants falsely and fraudulently misrepresented in their advertisements, promotional materials and other materials, among other things, the safety, potential side effects and convenience of Prempro;

- i. Whether defendants designed and manufactured a drug that was dangerously defective because its use leads to serious adverse health effects including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease and breast cancer;
- j. Whether defendants knew or should have known that the use of Prempro leads to serious adverse health effects;
- k. Whether defendants adequately tested Prempro prior to distribution and sales in the market place;
- l. Whether defendants continued to manufacture, market, distribute, and sell Prempro notwithstanding their knowledge of the drug's dangerous nature;
- m. Whether the warnings and information defendants provided with Prempro were adequate in warning of the potential hazards resulting from its use;
- n. Whether defendants knowingly omitted, suppressed or concealed material facts about the unsafe and defective nature of Prempro from government regulators, the medical community and/or the consuming public;
- o. Whether defendants' conduct constituted the knowing or intentional concealment, suppression, or omission of material information intended to be relied upon by others in connection with the sale of Prempro within the meaning of all states' Consumer Protection Statutes; and
- p. Whether the Class has been injured by virtue of defendants' violations of all states' Consumer Protection Statutes.
- 33. The questions of law and fact common to the Class predominate over any questions which may affect only individual members.

- 34. The claims of the plaintiff are typical of the claims of the Class because plaintiff and members of the Class were injured in the same manner by defendants' negligent and/or reckless conduct. Moreover, the events and conduct that give rise to the claims of plaintiff also give rise to the same claims of the Class.
- 35. Plaintiff will fairly and adequately protect the interests of the Class. There are no disabling conflicts of interests between plaintiff and the Class. The plaintiff is a part of the Class, possesses the same interests, and suffered the same injuries as the Class members, making her interests coextensive with those of the Class.
- 36. The Class is represented by experienced counsel well-qualified to handle this case. This lawsuit will be capably and vigorously pursued by the class representative and her counsel.
- 37. A class action is superior to other methods for the fair and efficient adjudication of the controversy, for reasons that include the following:
- a. The prosecution of separate actions by individual members of the Class creates a risk of inconsistent or varying adjudications with respect to members of the Class which would establish incompatible standards of conduct for defendants;
- b. The relief sought includes injunctive relief and declaratory relief with respect to the Class as a whole that would provide uniform relief to plaintiff and all persons similarly situated to plaintiff;
- c. Questions of law and fact common to the members of the Class predominate over any questions affecting only individual members and prosecution as a class action will eliminate possibility of duplicative litigation;

- d. A class action will provide redress for claims which would otherwise be too small to support the expense of individual, complex litigation; and
- e. The controversies alleged herein can be most efficiently litigated as a class action. The questions set forth above predominate over any questions affective only individual persons, and a Class Action is superior with respect to considerations of consistency, economy, efficiency, fairness and equity, to other available methods for the fair and efficient adjudication of the controversy.
- 38. Plaintiff, on behalf of herself and the Class, seeks a refund of and restitution for monies paid as a result of her purchases of Prempro, as well as all other ascertainable economic loss that occurred as a result of Defendants' wrongful and improper conduct in connection with the manufacture, marketing, distribution, testing, promotion, labeling and/or selling of Prempro. Plaintiff therefore seeks to disgorge Defendants of the monies inappropriately acquired by them as a result of their sales of Prempro.
- 39. Plaintiff, on behalf of herself and the Class, seeks equitable relief in the form of a Court-ordered and supervised medical monitoring program, funded by Defendants, to assist Plaintiff and the Class members in the early detection and treatment of illnesses caused by Prempro. Such a program would include the following:
- a. A method to notify individuals who ingested Prempro of the increased risk of harm that they have suffered as a result of the ingestion of Prempro;
- b. Provision for the accumulation and analysis of relevant medical and demographic information from Class members including, but not limited to, the results of all

appropriate diagnostic tests performed on Class members as part of a medical research and education fund;

- c. Provision for the creation, maintenance and operation of a medical registry in which relevant demographic and medical information concerning all Class members is gathered, maintained and analyzed;
- d. Provision for medical research concerning the incidence, prevalence, natural course and history, diagnosis and treatment of Prempro induced personal injuries; and
- e. Publication of, and other dissemination of, all such information to members of the Class and their physicians.
- 40. Class certification with respect to plaintiff's claims for relief through creation of a Court-supervised fund to provide medical research, education, monitoring and screening is appropriate because defendants have acted, or refused to act, on grounds generally applicable to the Class, making appropriate preliminary and final injunctive and declaratory relief consisting of medical monitoring and notice with respect to plaintiff and the Class members.

FRAUDULENT CONCEALMENT

- 41. Any applicable statutes of limitations have been tolled by the defendants' knowing and active concealment and denial of the facts as alleged herein. Plaintiff and Class members have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiff and Class Members could not reasonably have discovered the defective nature of Prempro prior to July 9, 2002.
- 42. Defendants are and were under a continuing duty to disclose the true character, quality and nature of Prempro to plaintiff and Class members. Because of their concealment of the

true character, quality and nature of Prempro, defendants are estopped from relying on any statute of limitations defense.

CLAIMS FOR RELIEF

COUNT I STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

- 43. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 44. The Defendants were engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Prempro in interstate commerce, which they sold an distributed throughout the United States, to Plaintiff and Class members.
- 45. The Plaintiff was using Prempro in a manner for which it was intended or in a reasonably foreseeable manner.
- 46. Prempro was expected to and did reach the Plaintiff and Class members without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed.
- 47. The Plaintiff and the members of the Class were not aware of, and reasonably could not have discovered, the dangerous nature of Prempro.
- 48. The Defendants' Prempro caused increased risks of personal injury and harm upon consumption, and therefore constitute a product unreasonably dangerous for normal use due to their defective design, defective manufacture, and the Defendants' misrepresentations and inadequate facts disclosed to the Plaintiff and the members of the Class.

- 49. As a direct and proximate result of Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distribution Prempro in interstate commerce, Plaintiff and class members are at an increased risk of developing injuries, including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease and breast cancer and have suffered compensatory and punitive damages in an amount to be proven at trial.
- 50. The Defendants, therefore, are strictly liable to the Plaintiff and members of the Class. Additionally, Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. The Plaintiff and members of the Class, therefore, are entitled to punitive damages. All of the Defendants are liable to Plaintiff and to members of the Class jointly and severally for all general, special, and equitable relief to which the Plaintiff and the Class are entitled by law.

COUNT II NEGLIGENCE

- 51. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 52. The Defendants have a duty to exercise reasonable care to properly design, research, develop, test, inspect, label and prepare for use the drug, Prempro, which was introduced into the stream of commerce, including a duty to insure that the product does not cause users to suffer from unreasonable, dangerous or untoward adverse side effects.
- 53. The Defendants owed a duty to notify consumers of the need for diagnostic testing prior to Prempro's withdrawal from the market.

- 54. The Defendants breached that duty by failing to exercise ordinary care in the design, research, development, manufacture, sale, testing, quality assurance, quality control and/or distribution of Prempro into interstate commerce, because the pharmaceutical defendants knew or should have known that the product, Prempro, created the risk of unreasonable, dangerous or untoward adverse side effects.
- 55. The Defendants knew, or in the exercise of reasonable care, should have known, that the product, Prempro, was of such a nature that, if not properly manufactured, labeled, tested, and inspected before being sold, they were likely to cause injury to the products' users.
- 56. The Defendants were negligent in the design, manufacture, testing, promotion, advertising, warning, labeling, marketing and sale of Prempro in that they:
- a. Failed to use due care in the designing, testing, and manufacturing of Prempro to prevent the aforementioned risks to individuals when Prempro was used for the treatment of HRT;
- b. Failed to accompany their product with proper warnings regarding all possible adverse side effects associated with the use of Prempro and the comparative severity and duration of such adverse effects;
- c. Failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Prempro;
- d. Failed to provide adequate training and information to medical care providers for the appropriate use of Prempro;
- e. Failed to warn the plaintiff and her/his healthcare provider(s), prior to actively encouraging and promoting the sale of Prempro, either directly or indirectly, orally or in writing, about the following:

- (i) the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease and breast cancer and other adverse side effects;
 - (ii) the possibility of becoming disabled as a result of the use of the drug;
- (iii) the adverse side effects associated with the use of the drug, including,
 but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease
 and breast cancer; and
 - f. Were otherwise careless and/or negligent.
- 57. Despite the fact that the Defendants knew or should have known that Prempro caused unreasonable and dangerous side effects which many users would be unable to remedy by any means, the pharmaceutical defendants continued to promote and market Prempro to consumers, including the plaintiff, when safer and more effective methods of controlling high cholesterol were available.
- 58. The Defendants knew or should have known that consumers such as the plaintiff would forseeably suffer injury as a result of the pharmaceutical defendants' failure to exercise ordinary care as described herein.
- 59. Plaintiff and the Classes are entitled to punitive damages because the Defendants' failure to warn was reckless and without regard for the public's safety and welfare. The pharmaceutical defendants misled both the medical community and the public at large, including the plaintiff, by making false representations about the safety of their products. The Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side

effects associated with the use of Prempro despite available information demonstrating that this product was likely to cause serious and sometimes fatal side effects to users.

- 60. The Defendants were or should have been in possession of evidence demonstrating that their product caused serious side effects. Nevertheless, they continued to market the product by providing false and misleading information with regard to its safety and efficacy.
- 61. The Defendants' actions, described above were performed willfully, intentionally and with reckless disregard for the rights of the plaintiff and the public.
- 62. As a result of the Defendants' conduct, plaintiff and the Classes suffered the injuries and damages specified herein.
- 63. Accordingly, plaintiff and the Classes seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

COUNT III UNJUST ENRICHMENT

- 64. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 65. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefitted from the purchase Prempro by the Plaintiff and the Class.
- 66. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiff and the Plaintiff Class, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff and the Plaintiff Class were not receiving a product of the quality, nature, or fitness that had been represented by Defendants or that Plaintiff and the Plaintiff Class, as reasonable consumers, expected.

67. By virtue of the conscious wrongdoing alleged in this Complaint, Defendants have been unjustly enriched at the expense of the Plaintiff and the Plaintiff Class, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT IV MEDICAL MONITORING

- 68. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 69. Plaintiff and class members have been significantly exposed to proven hazardous substances through the intentional, negligent, or wrongful actions of the Defendants.
- 70. As a proximate result of this exposure, Plaintiff and class members suffer significantly increased risks of developing serious, latent diseases.
- 71. That increased risk makes periodic diagnostic medical examinations reasonably necessary.
- 72. Monitoring and testing procedures exist which make the early detection and treatment of disease possible and beneficial.
- 73. Defendants' actions render them liable to pay all costs of a comprehensive courtsupervised medical monitoring program, to provide diagnostic and treatment services for the benefit of the class.
- As a direct and proximate result of Defendants' manufacturing, creating, designing, 74. testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Prempro, in interstate commerce, Plaintiff and class members are at an

increased risk of developing injury and/or death and have suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT V BREACH OF EXPRESS WARRANTY

- 75. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 76. Defendants expressly warranted to Plaintiff, by and through statements made by Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Prempro was safe, effective, fit and proper for its intended use.
- 77. In using Prempro, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.
- 78. As a direct and proximate result of Defendant's breaches of warranties, Plaintiff and class members are at an increased risk of developing injury and/or death and have suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT VI BREACH OF IMPLIED WARRANTY

- 79. The plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length.
- 80. Prior to the time that Prempro was used by Plaintiff, Defendants impliedly warranted to Plaintiff that Prempro was of merchantable quality and safe and fit for the use for which it was intended.

- 81. Plaintiff and members of the Class were and are unskilled in the research, design and manufacture of Prempro and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Prempro.
- 82. Prempro was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.
- 83. As a direct and proximate result of Defendants' breaches of warranties, Plaintiff and class members are at an increased risk of developing injury and/or death and have suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT VII CORPORATE RESPONSIBILITY: JOINT VENTURES, PARENT/SUBSIDIARIES, AND/OR SUCCESSOR CORPORATION

- 84. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs.
- 85. As a result of their participation in various joint ventures, parent/subsidiary relationships, and/or successor corporations, Defendants are liable to the Plaintiff.
- 86. As a result of their negligent supervision and actual supervision of various joint ventures, parent/subsidiary relationships, and/or successor corporations. Defendants are liable to Plaintiff.
- 87. As a result of the invalidity of various indemnification agreements, Defendants are liable to Plaintiff.
- 88. Defendants are liable to Plaintiff, as alter egos of their joint ventures, parent/subsidiary relationships, and/or successor corporations.

COUNT VIII **PUNITIVE DAMAGES**

- 89. Plaintiff incorporates by reference all preceding paragraphs as if set forth herein.
- 90. Defendants acted wantonly, recklessly, intentionally, and/or with conscious indifference to the rights, safety and welfare of the Plaintiff and are therefore liable to Plaintiff for punitive and exemplary damages in accordance with state law.

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, pray that the Court enter judgment against defendants Wyeth individually and d/b/a Wyeth Research, and in favor of the Plaintiff and the Classes, and to award the following relief:

- Certification of the proposed Classes and Subclasses; a.
- b. Declare that Prempro is dangerous and defective, and that Defendants are financially responsible for notifying all members of the Class of the defective drugs;
- c. Declare that Defendants must disgorge, for the benefit of the Class, all or part of their ill-gotten gains and benefits received from the sale of Prempro, and/or make full restitution to Plaintiffs and the members of the Class;
- d. Determine each Defendant's liability for punitive/exemplary damages to the extent necessary and appropriate to punish and deter the conduct complained of herein;
- Award compensatory and punitive damages for the acts complained of herein. e. in an amount to be proven at trial;
- f. Award attorneys' fees and costs, plus interest, as allowed by law, and/or from a common fund created hereby;
- Provide nationwide consumer notice, at Defendants' expense, regarding g. medical monitoring;

- h. Order Defendants to fund Court-supervised or Court-approved programs to medically monitor Class members, to pay or reimburse the cost of medical treatment of Class members; and
- i. Order such other or further judicial determinations, and relief, as may be appropriate under the circumstances under the Court's exercise of its equitable jurisdiction and inherent authority in this proceeding.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of herself and all others similarly situated, hereby demands a jury trial on all claims so triable in this action.

Dated: July 17, 2002 RESPECTFULLY SUBMITTED,

By:

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- and -

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